APR 30 2008 2

K080924

PREMARKET NOTIFICATION [510(K)] SUMMARY

Date Prepared:	March 31, 2008
Submitter:	St. Jude Medical, CRMD
Address:	15900 Valley View Court Sylmar, CA 91324
Phone:	818 493-2960
Fax:	818 493-3615
Contact Person:	Colleen Canan
Trade Name/Proprietary Name:	CPS Mond™ RVOT Stylet
Common Name:	Mond™ Stylet Model Numbers: 4140, 4141, 4150, and 4151
Classification:	Class II, 21 CFR 870.1380
Legally marketed device to which your firm is claiming equivalence:	St. Jude Medical Model 4090 and 4091 approved under. P960013/S15 and S-75-X stylets approved under P950022/S17.

Device Description:

The St Jude Medical (SJM) Mond RVOT Stylet is an accessory implant tool, intended for use in the placement of SJM right ventricular active fixation leads. The Mond stylet is configured in a modified "J" shape designed to position the leads in the RVOT. The stylet uses the same materials and similar manufacturing processes as the currently approved J (4090 and 4091) bradycardia stylets and the S-75-X tachycardia stylets.

The Mond™ RVOT Stylet indication for use is as follows:

The St. Jude Medical Mond™ RVOT Stylet is designed to place SJM right ventricular active fixation leads in the right ventricular outflow tract.

Technological Characteristics of the Device Compared to the Predicate Device:

The Mond™ RVOT Stylet uses similar technology; has similar intended use, functions, materials and method of operation of the following predicate devices.

- St. Jude Medical Model 4090 and Model 4091 approved under.P960013/S15 on April 7, 2006.
- St Jude Medical Model S-75-X approved under P950022/S17 on July 1, 2003.

Summary of Studies:

Device comparison testing was performed to support equivalency of the CPS Mond™ RVOT Stylet with the predicate devices, SJM Models 4090 and 4091 and S-75-X. In addition verification and validation activities necessary to ensure that the specified Mond™ RVOT stylet product and system requirements were fulfilled, and to ensure that the product design conforms to the user needs and intended use were identified and successfully performed. Product verification was successfully performed and is documented in QTR 2170 (**appendix 7**).

Biocompatibility:

There is no change to the Mond™ RVOT stylet materials in comparison to the predicate 4090/4091 stylets other than the ink on the button which does not have blood and tissue contact by design. For these reasons, no additional biocompatibility testing were considered necessary per ISO 10993-1.

Sterilization Validation:

The CPS Mond™ RVOT Stylet is sterilized using the same validated 100% Ethylene Oxide (EtO) sterilization process as the 4090 and 4091 stylet kits. The sterility assurance level (SAL) is 10^{-6}. Sterilization validation report is provided in appendix 6.

Conclusion:

St. Jude Medical considers the CPS Mond™ RVOT Stylet to be substantially equivalent to the legally marketed predicate and referenced devices. The results of the tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use.

K080924-2of2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC -9 2008

St. Jude Medical
c/o Ms. Colleen Canan
Regulatory Affairs
15900 Valley View Court
Sylmar, CA 91342

Re: K080924
Trade/Device Name: Mond™ RVOT Stylet Models 4140, 4141, 4150, 4151
Regulation Number: 21 CFR 870.1380
Regulation Name: Catheter Stylet
Regulatory Class: Class II (two)
Product Code: DRB
Dated (Date on orig SE ltr): March 31, 2008
Received (Date on orig SE ltr): April 2, 2008

Dear Ms. Canan:

This letter corrects our substantially equivalent letter of April 30, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting) (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vachner

Bram D. Zuckerman, M.D.
Director, Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K080924

Device Name: CPS Mond™ RVOT Stylet

Indications For Use:

The CPS Mond™ RVOT Stylets are indicated for:

- The St. Jude Medical Mond™ RVOT Stylet is designed to place St. Jude Medical right ventricular active fixation leads in the right ventricular outflow tract.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080924